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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/557,955	04/25/2000	Yvonne E. Penfold	IMIN.P-027	8900

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EXAMINER

DUFFY, PATRICIA ANN

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 11/14/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/557,955

Applicant(s)  
Penfold Et A

Examiner  
Patricia A. Duffy

Art Unit  
1645



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Jul 10, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 2-20 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 12-20 is/are allowed.
- 6) ☒ Claim(s) 2-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 2 6) ☐ Other:

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*Response to Amendment*

1. The amendment and response filed 7-10-02 has been entered into the record.
2. The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

*Rejections Withdrawn*

3. Any rejection not reiterated herein is withdrawn based on Applicants arguments.

*New Rejections*

4. Claims 2-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claim 9 and every claim dependent thereon, the claim recites "An assay device of the type...". However, the claim never states what the assay device specifically comprises and therefore it is completely unclear as to what, if any, of the recited elements are positively included in the claimed assay device. Applicants are directed to amend the claims to recite --An assay device comprising--.... followed by any elements that the assay device must possess. Further, the claim references "said first specific binding agent" but never recites a "first specific binding agent".

As to claim 2 and every claim dependent thereon, the recitation of "the first specific binding agent" lacks antecedent basis in claim 9, because claim 9 never defines such.

As to claims 6-8 and any claim dependent thereon, the phrase "coloured latex particles" lacks antecedent basis in the claims from which it depends.

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5. Claims 12-20 are allowed.

The patentable element of the claimed invention an assay device is the particulate direct label co-sensitized with a first specific binding agent for an analyte or analyte/analogue and a non-specific protein which can participate in a control reaction with another specific binding agent which does not bind to said first specific binding agent nor participate in the formation of a complex by means of which detection of said analyte or analyte/analogue is accomplished in said detection zone. Pawlak et al (U.S. Patent No 5,770,460) and Huang et al (U.S. Patent No. 6,368,876) are the closest prior art of record. While each of Pawlak et al and Huang et al teach analyte specific binding agents and control agents (i.e. the instant non-specific protein that can participate in a control reaction with another specific binding agent) immobilized on different particulate direct labels in the same assay, neither Pawlak et al or Huang et al provide any motivation for placing both the analyte specific binding agent and the control agent on the same particulate direct label. Neither Pawlak et al or Huang et al alone or in combination with any art of record provide motivation for this critical patentable aspect of the claimed invention.

#### *Status of Claims*

6. Claims 12-20 are allowed. All other claims stand rejected.

#### *Conclusion*


7. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy, Ph.D. whose telephone number is (703) 305-7555. The examiner can normally be reached on Monday-Thursday and Saturday from 10:30 AM to 7:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached at (703) 308-3909.

Patricia A. Duffy, Ph.D.  
November 14, 2002

  
Patricia A. Duffy, Ph.D.  
Primary Examiner  
Group 1600